DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 18 1998

Rec'd 3/26/98 jb

Mr. Robert J. Lang
Director, Quality Operations
Novartis Nutrition Corporation
1541 Park Place Boulevard
St. Louis Park, Minnesota 55416-1541

Dear Mr. Lang:

This is in response to your letter of February 18, 1998 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Novartis Nutrition Corporation is making the following statements, among others, for the product Resource Renal Creme Beverage:

"Oral liquid nutrition for individuals with electrolyte restrictions"
"...non-drug method to help constipation"
"...often a deficiency in dialysis patients"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claims that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, in that they are intended to treat, prevent, or mitigate the consequences of renal disease and to treat, prevent, or mitigate the consequences of treatment (i.e., dialysis) of renal disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET154

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Minneapolis District Office, Compliance Branch, HFR-MW340

cc:
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file, OSN#57505)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:3/17/98
init:GCF-1:DDorsey:3/17/98
f/t:rjm:HFS-456:3/17/98:57505.adv:disc27

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Robert J. Lang
Director
Quality Operations

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RECEIVED 3/4/98

Office of Special Nutritionals
Center for Food Safety and Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204

February 18, 1998

Section 403(r)(6) Notification

In accordance with the requirements of section 403(r)(6) of the Federal Food Drug and Cosmetic Act, Novartis Nutrition is providing this notification that it has begun using the following statements on the package (or associated labeling):

- "ORAL LIQUID NUTRITION FOR INDIVIDUALS WITH ELECTROLYTE RESTRICTIONS"

"Helps rebuild protein stores"

"Contains 3 g Benefiber, a soluble dietary fiber... and non-drug method to help manage constipation"

"31 g of carnitine per serving... often a deficiency in dialysis patients"

of the following product:

Resource Renal Creme Beverage

This product is sold through food service channels for use in hospitals and nursing homes, and is not intended for retail sale.

The above statements are accompanied by the statutory disclaimer language, and the product is identified as a dietary supplement.

Robert J. Lang

ISO 9001